

REMARKS

Claims 68 and 73-75 were pending in the present application. Claims 68 and 75 have been amended. New claims 76 and 77 have been added. Support for the amendments to the claims and new claims can be found throughout the specification and claims as filed. Specifically, support for the amendments to claim 68 can be found at least at page 12, lines 13-30; page 13, lines 10-21; page 14, lines 19-28; and page 16, lines 8-14. Support for the amendments to claim 75 can be found at least at page 1, lines 11-14. Support for new claim 76 can be found at least at page 12, lines 1-28. Finally, support for new claim 77 can be found at least at page 14, lines 19-28. No new matter has been added.

Rejection of Claims 68 and 73-75 Under 35 U.S.C. § 112, 1st Paragraph, Enablement

The Examiner has rejected claims 68 and 73-75 under 35 U.S.C. § 112, 1st paragraph as allegedly failing to comply with the enablement requirement. Specifically, the Examiner is of the opinion that “[t]he instant claims fail to recite the culturing conditions: for example, culture media contents, growth factors, culture environment that leads to the synthesis of the claimed extracellular matrix components” (see the pending Non-Final Office Action at page 6). The Examiner is further of the opinion that “[a]ll of applicants working examples that relate to the instant claims rely upon cells cultured, at least at some point, under the culture conditions set forth in Example 1. Example 1 uses newborn calf serum in the culture media, and thus does not provide a working example of the instant claims” (see the pending Non-Final Office Action at pages 7-8).

Applicants respectfully traverse the rejection and submit that the specification provides several working examples of the methods recited in the pending claims. For example, at least examples 15 and 16 of the specification teach working examples of appropriate methods. In addition, the specification teaches a person having ordinary skill in the art how to alter the conditions from those specifically described in the examples (see, for example, the teachings regarding chemically defined culture media preparation and use at page 11, lines 25 to page 19, line 6).

Nevertheless, solely for purposes of expediting prosecution, Applicants have amended claim 68 to specifically recite certain essential media components. In addition, Applicants are submitting concurrently herewith an executed Declaration under 37 C.F.R. § 1.132 from Dr.

Vincent Ronfard , a co-inventor of the present application (hereinafter, the ‘Ronfard Declaration’). As explained in the declaration, Dr. Ronfard and his group performed a series of experiments which varied the components of the culture medium to determine which components are essential for the production of a reasonable amount of extracellular matrix. Based on the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claim 75 Under 35 U.S.C. § 112, 2nd Paragraph

The Examiner has rejected claim 75 under 35 U.S.C. § 112, 2nd paragraph as allegedly being indefinite for providing insufficient antecedent basis for “the product.” Applicants have amended claim 75 to replace “the product of” with “A cultured tissue construct produced using” the method recited in claim 68. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claim 75 Under 35 U.S.C. § 101

The Examiner has rejected claim 75 under 35 U.S.C. § 101 as allegedly being drawn to non-statutory subject matter for comprising natural collagen. Applicants have amended claim 75 so that it is directed to a cultured tissue construct. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection as it pertains to the amended claim.

Provisional Claim Rejections – Obviousness-type Double Patenting

The Examiner has rejected claims 68 and 73-75 on the grounds of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 31, 33, and 39-51 of copending Application No. 11/932,052. Applicants agree to file an appropriate terminal disclaimer at such time as the pending claims are indicated to be allowable.

CONCLUSION

The application is now believed to be in proper condition for allowance and a Notice to that effect is respectfully requested. The Examiner may address any questions raised by this submission to the undersigned at (617) 832-1000. If any fees are due, the Commissioner is hereby authorized to credit any overpayment or charge any deficiencies to Deposit Account No. **Deposit Account No. 06-1448, Reference No. OGA-010.02.**

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Respectfully submitted,

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